Patient Information Form

For adults (≥16 years old)

HemoNED Registry: National registry of patients with hemophilia and related disorders.

Dear Sir / Madam,

We ask you to join HemoNED, the national registry of patients with hemophilia and related disorders. You decide whether you want to join. Before taking the decision, it is important to know more about the registry. Read this patient information form carefully. Discuss it with your partner, friends or family. If you have any questions after reading the information, you can contact your doctor.

What is the purpose of the registry?

The HemoNED registry aims to survey the care and treatment of all patients in the Netherlands with hemophilia, Von Willebrand disease, very rare clotting factor deficiencies and hereditary platelet disorders. In case of these rare diseases, for which an effective but costly treatment is available, a national patient registry is an essential tool to monitor the treatment and improve the quality of care. By comparing treatments and outcomes we can search for the best treatment. Patients can be compared with each other, but also comparison between treatment centers and with other countries is possible. After anonimisation the medical information within the registry will be used for different purposes:

- To survey the total number of patients by diagnosis, clotting factor use and treatment outcomes (including bleedings, joint status, quality of life).
- To report adverse events to Lareb (Netherlands pharmacovigilance centre) and to EUHASS (European Hemophilia Safety Surveillance System).
- To survey the quality of care and the effectiveness of treatments.
- Providing data for:
    - summary reports
    - scientific research
    - studies on the safety and effectiveness of new drugs.

What is being registered?

The data for the registry will be obtained in two ways: 1) your doctor will enter information from your medical record and 2) via a digital infusion log you can enter information yourself (for patients who administer medication at home).

<u>1) Medical record</u>

The medical data relevant for your blood clotting (such as diagnosis, treatment, treatment outcomes, and side effects) that are available in your medical record at your hemophilia treatment center will be entered into the HemoNED registry together with some personal information (name, citizen service number, patient number, date of birth). The personal data within the registry can only be viewed by yourself and by your own hemophilia treatment center. The medical data will be separated from your personal data and stored anonymously, to make sure they cannot be traced back to you when the data is used for purposes other than your regular treatment.

2) Digital infusion log

When you administer medication at home, we want to ask you to start using a digital infusion log; this replaces the paper infusion logs or existing electronic applications. The digital infusion log is available in the form of a software application (app) for the smartphone and/or tablet (for iOS and Android systems). If you do not want or can use an app, we provide the opportunity to enter your information through a website. In the digital infusion log you can enter your infusions, bleedings and the location of bleedings. In the long term, we can also examine the treatment outcomes through online questionnaires about for example your quality of life. The entries are automatically sent to the registry via a secure Internet connection, so your doctor can also view the data and discuss them with you during a consultation. The app will not warn your doctor if you enter a bleeding. In acute situations, such as the occurrence of severe bleeding, you should therefore contact your doctor yourself.

What is expected of you?

For participation in the registry, we need your written permission; the informed consent form can be found in Annex B. When you are going to use the digital infusion log, your doctor will sign you up with your e-mail address and 06-number (Annex C). You are then able to install the app on your smartphone and/or tablet, or log in via the website on your computer. Then you can enter your infusions and data on any bleeding.

What are the possible benefits and risks of participation in this registry?

Benefits

When using the digital infusion log you can see a brief overview of your infusions and bleedings through the app, and a more extensive overview when logging in to the website. This can be supportive for your home treatment. During a consultation with your doctor the digital infusion log also provides a quick and clear overview regarding your actual infusions and bleedings occurred.

For the future, your anonymous medical data, along with those of other patients, can provide useful information through research studies. Annually, an summary report of the available registry data will be published on the website (https://hemoned.nl).

Risks

Participation in the registry does not involve risks. The registry will follow your regular care. The digital infusion log replaces the paper or electronic infusion logs that are already used.

What happens if you do not wish to participate?

You decide whether you want to participate in the registry. Participation is voluntary. If you decide not to participate, you don't need to do anything, nor do you have to say why you do not want to participate. This does not affect your treatment. You are then, however, not able to use the digital infusion log. If you do participate, you can always withdraw later on. In that case, you can inform your doctor. Data that have been made anonymous, for example, for the purpose of research, can not be removed because they are no longer traceable to you.

How is your privacy guaranteed?

Your data are subject to medical professional secrecy. Your personal data in the registry are only visible to your doctor. Each hemophilia treatment center can review and use the data of

its own patients to evaluate the treatments. For other purposes, the medical data in the registry are stored by a code in a central database; only your doctor knows which code belongs to you. When information from the registry is provided to other parties, like research groups or pharmaceutical companies, the data will be anonymized, meaning it is by no means traceable to you.
The database is build and hosted by the company Medical Research Data Management (MRDM). MRDM meets the requirements of the General Data Protection Regulation. MRDM signed a Data Processing Agreement with all hospitals involved, which means that they are allowed to process patient data. MRDM employees have very limited access to the database.
Your data are stored in the registry for a lifetime. When you pass away, your personal information will be retained for 15 years. The coded data are kept as long as the registry exists.
When you are going to use the digital infusion log on your smartphone and/or tablet, it is important that the data is stored safely. The data that you enter will be immediately sent to the registry through a secure Internet connection. A brief overview of the information entered can be seen on your smartphone/tablet. In the absence of an Internet connection (only) the most recently entered information will be temporarily stored on the smartphone until a connection becomes available. To further ensure data security, we ask users to secure both the smartphone/tablet and the app with a numeric code.

Which parties are involved in the registry?

All Dutch certified hemophilia treatment centers participate in the HemoNED registry. The registry is managed by the HemoNED Foundation, which is assisted by a Steering Committee; the two bodies consist of representatives of the clinicians (NVHB) and of the patient organization (NVHP). The registry is set up with a grant from ZonMw (Ministry of Health, Welfare and Sport). For the long-term, funding is sought by health insurers and the pharmaceutical companies which produce clotting factor products.

Cooperation with researchers and companies

Anonymized data from the registry will be made available for scientific research. The Steering Committee of the HemoNED Foundation decides on submitted research proposals. In the future a link will be made between the registry and the national hemophilia biobank. This biobank will be set up by the 'Hemofilie in Nederland (HiN-6)' study group; they will inform you about this and ask your informed consent.
Also (commercial) companies such as pharmaceutical companies, health insurers and the government may request information from the registry, for example, for research studies into the safety and effectiveness of drugs. This information is made available only when the Steering Committee positively decides on the research proposal. Only anonymous data is available to third parties. All research studies should be beneficial to health care. Any financial contributions will be used for the development and maintenance of the registry. You will not be entitled to any future financial benefit.

How to deal with questions or complaints?

If you have questions or complaints about the registry, you can report this to your doctor. In Annex A you can find the contact person in your treatment center. If you would like an independent advice on your participation in the registry, you can contact an independent expert. This is dr. M.V. Huisman, is available by phone, 071 - 526 3761 or by e-mail,

M.V.Huisman@lumc.nl. If you are dissatisfied with the way things are going and you want to file a complaint, please contact Patient Services (see Annex A for contact details).

More information

More information about the HemoNED registry and the digital infusion log can be found on our website: https://hemoned.nl. The HemoNED Foundation can be reached by phone, 071 - 526 1893 or by e-mail, info@hemoned.nl.

Annexes

A. Contact details local hemophilia treatment center
B. Informed Consent Form HemoNED registry
C. E-mail address(es) and 06-number(s): only necessary if you want to start using the digital infusion log

Annex A: Contact details local hemophilia treatment center

Principal investigator:
Department:
Address:
E-mail:
Phone:

Complaints
If you are dissatisfied with the way things are going and you want to file a complaint, please contact Patient Services.

Address:

E-mail:
Phone:

Annex B: Informed Consent Form HemoNED registry

For adults (≥16 years old)

HemoNED Registry: National registry of patients with hemophilia and related disorders.

I have read the Patient information form. I could ask additional questions and my questions have been answered sufficiently. I had enough time to decide if I would participate.

I know that participation is completely voluntary, and that I can decide at any time to withdraw without providing a reason.

I know that my personal information can only be seen by employees of my hemophilia treatment center. The Steering Committee decides whether my - exclusively anonymized - registry data will be made available to others, such as scientific researchers or pharmaceutical companies.

I know that, after my death, my personal data will be retained for 15 years and the anonymized data for as long as the registry exists.

I hereby give consent to include my medical and personal information in the HemoNED registry. I give permission to use my information for the purposes stated in the Patient information form.

Name: ..... Date of birth: ..... / ..... / .....

Date:……/……..…/……. Signature: .....

You can hand in this form with your doctor. If you have questions about the use of your data or if you want to have your data removed from the registry, please contact your doctor.

- To complete by the doctor -

I hereby declare that I have fully informed this person about the registry.

If information becomes available that could affect the consent of the person, I will notify him/her promptly.

Name doctor: .....

Date:……/……..…/……. Signature: .....

Annex C: E-mail address(es) and 06-number(s)
(Only necessary if you want to start using the digital infusion log (VastePrik App or website) to register your treatment, bleedings or side effects)

Digital infusion log
If you want to start using the digital infusion log for home treatment (in the form of an app for your smartphone and/or via the computer), please fill in your e-mail address and 06-number below. This requires your doctor to sign you up for use of the app and/or the website.

E-mail address: ……

06-number:……

Relationship to the subject: Participant himself/Participant herself/Father/Mother/Partner/ Other Family member/Guardian (please circle as appropriate)

If other people also want to use the digital infusion log for registering your home treatment, you can request an account for them.

Account 2:

Relationship to the subject: Participant himself/Participant herself/Father/Mother/Partner/ Other Family member/Guardian (please circle as appropriate)

E-mail address: ……

06-number:……

Account 3:

Relationship to the subject: Participant himself/Participant herself/Father/Mother/Partner/ Other Family member/Guardian (please circle as appropriate)

E-mail address: ……

06-number:……

Account 4:

Relationship to the subject: Participant himself/Participant herself/Father/Mother/Partner/ Other Family member/Guardian (please circle as appropriate)

E-mail address: ……

06-number:……

The e-mail addresses and 06-numbers will be linked to the app. A change of e-mail address or 06-number must be communicated to your doctor in writing.